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REMARKS35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 1-7

The rejection of claims 1-7 is respectfully traversed.

Claim 1 claims "[a] method of cutting a plug of tissue from the wall of a blood vessel, the method comprising: piercing the wall of the blood vessel, at a location in the wall through which blood previously had been substantially prevented from escaping, with a piercing element to create an opening therethrough; cutting a plug from the wall of the blood vessel around the opening to create a hole in the blood vessel; and inserting a trocar around the piercing element and into the hole in the wall of the blood vessel."

In contrast, U.S. Pat. No. 5,192,294 to Blake III ("Blake") does not expressly or inherently describe each and every element of claim 1. First, Blake does not expressly or inherently describe "piercing the wall of the blood vessel, at a location in the wall through which blood previously had been substantially prevented from escaping, with a piercing element to create an opening therethrough." (emphasis added). Instead, Mayenberger describes inserting an element of the tool into a preexisting incision in the blood vessel wall. (Blake; e.g., col. 5, lines 34-45) (emphasis added). The Office Action characterizes the mandrel 7 of Blake as being analogous to the claimed piercing element. (Office Action, page 2). Blake discloses a mandrel 7, where "[t]he distal end of mandrel 7 further comprises a

reduced diameter stem 55 terminated by a circular disc 56.” (Blake; col. 5, lines 17-18; Figures 1-5). A “distal portion 57 comprising a distally tapered truncated cone” may be part of the disc 56. (Blake; col. 5, lines 30-33; Figures 1-5). “In the process of using the vascular punch, of the invention, an incision is made in the blood vessel the length of the incision being smaller than the diameter of the hole to be made therein, and the disc inserted, by means of conical portion 57 (if present) into, the vessel.” (Blake; col. 5, lines 34-38). Thus, the mandrel 7 is inserted into the blood vessel through a pre-existing incision in the blood vessel wall. Such a pre-existing incision in the wall of a blood vessel necessarily allows blood to escape, directly contrary to the express requirement of claim 1 of piercing the wall at a location “through which blood previously had been substantially prevented from escaping.” (emphasis added).

Second, Blake does not expressly or inherently describe both the claimed “cutting a plug from the wall of the blood vessel around the opening to create a hole in the blood vessel; and inserting a trocar around the piercing element and into the hole in the wall of the blood vessel.” (emphasis added). Blake discloses cutting tissue from the wall of a blood vessel as a result of interaction between the mandrel 7 and the blade drum 6. However, the method of Blake ends after that tissue has been removed. Nowhere does Blake disclose “inserting a trocar around the piercing element and into the hole in the wall of the blood vessel” separately from the “cutting” step.

Thus, Blake does not expressly or inherently describe each and every element of claim 1, and claim 1 is believed to be in condition for allowance. Claims 2-7 depend from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

#### Claims 8-15

The rejection of claims 8-15 is respectfully traversed.

Claim 8 claims “[a] method for making an opening in a vessel, comprising: piercing the wall of the vessel with a piercing element; retracting said piercing element at least partially into a tube having a lumen; and moving said piercing element away from the longitudinal centerline of said tube.” (emphasis added).

In contrast, Blake does not disclose “retracting said piercing element at least partially into a tube having a lumen; and moving said piercing element away from the longitudinal centerline of said tube.” (emphasis added). The Office Action implicitly admits as much, because it does not address this limitation of claim 8. The mandrel 7 of Blake only moves linearly along the longitudinal centerline of the blade drum 6. (e.g., col. 5, line 46 through col. 6, line 6; Figures 2-3). Indeed, the inner diameter of the blade drum 6 and the outer diameter of the mandrel 7 are substantially the same, such that the mandrel 7 cannot be moved away from the longitudinal centerline of the blade drum 6 as required by claim 8. (e.g., Figures 2-3). Thus, Blake does not disclose the claimed “retracting said piercing element at least partially into a tube having a lumen; and moving said piercing element away from the longitudinal centerline of said tube.”

As a result, Blake does not expressly or inherently describe each and every element of claim 8, and claim 8 is believed to be in condition for allowance. Claims 9-15 depend from claim 8, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

#### Claims 16-23

The rejection of claims 16-23 is respectfully traversed.

Claim 16 claims “[a] method for making an opening in the wall of a hollow tissue structure, comprising: piercing the wall of the hollow tissue structure, at a location in the wall through which fluid previously had been substantially prevented from escaping, with a

piercing element to create an opening therethrough; retracting the piercing element toward an opening in a body to cut a tissue plug from the wall of the hollow tissue structure; and capturing the tissue plug with said piercing element.." (emphasis added).

The discussion above with regard to claim 1 is equally applicable here. Blake fails to describe the claimed "piercing the wall of the hollow tissue structure, at a location in the wall through which fluid previously had been substantially prevented from escaping." As a result, Blake does not expressly or inherently describe each and every element of claim 16, and claim 16 is believed to be in condition for allowance. Claims 17-23 depend from claim 16, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

**REQUEST FOR ALLOWANCE**

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



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